

105TH CONGRESS
1ST SESSION

S. 88

To permit individuals to continue health plan coverage of services while participating in approved clinical studies.

IN THE SENATE OF THE UNITED STATES

JANUARY 21, 1997

Ms. SNOWE introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

A BILL

To permit individuals to continue health plan coverage of services while participating in approved clinical studies.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Improved Patient Ac-
5 cess to Clinical Studies Act of 1997”.

6 **SEC. 2. COVERAGE FOR INDIVIDUALS PARTICIPATING IN**
7 **APPROVED CLINICAL STUDIES.**

8 (a) AMENDMENTS TO ERISA.—Subpart B of part 7
9 of subtitle B of title I of the Employee Retirement Income
10 Security Act of 1974 (as added by section 603(a) of the

1 Newborns’ and Mothers’ Health Protection Act of 1996
 2 and amended by section 702(a) of the Mental Health Par-
 3 ity Act of 1996) is amended by adding at the end the fol-
 4 lowing new section:

5 **“SEC. 713. COVERAGE FOR INDIVIDUALS PARTICIPATING IN**
 6 **APPROVED CLINICAL STUDIES.**

7 “(a) PERMITTING PARTICIPATION IN APPROVED
 8 CLINICAL STUDIES.—A group health plan, and a health
 9 insurance issuer offering health insurance coverage in con-
 10 nection with a group health plan, may not deny (or limit
 11 or impose additional conditions on) the coverage of items
 12 and services furnished to an enrollee if—

13 “(1) the enrollee is participating in an approved
 14 clinical study,

15 “(2) the items and services are furnished ac-
 16 cording to the design of the study or to treat condi-
 17 tions resulting from participation in the study, and

18 “(3) the items and services would otherwise be
 19 covered under the plan except for the fact that they
 20 are provided in connection with participation in such
 21 a study.

22 Such a plan or issuer may not discriminate against an
 23 enrollee on the basis of the enrollee’s participation in such
 24 a study.

1 “(b) CONSTRUCTION.—Nothing in subsection (a)
2 shall be construed as requiring a group health plan, or
3 a health insurance issuer offering health insurance cov-
4 erage in connection with a group health plan, to provide
5 for payment for items and services normally paid for as
6 part of an approved clinical study.

7 “(c) APPROVED CLINICAL STUDY DEFINED.—In this
8 section, the term ‘approved clinical study’ means—

9 “(1) a research study approved by the Sec-
10 retary of Health and Human Services, the Director
11 of the National Institutes of Health, the Commis-
12 sioner of the Food and Drug Administration, the
13 Secretary of Veterans Affairs, the Secretary of De-
14 fense, or a qualified nongovernmental research entity
15 (as defined in guidelines of the National Institutes
16 of Health), or

17 “(2) a peer-reviewed and approved research
18 program, as defined by the Secretary of Health and
19 Human Services, conducted for the primary purpose
20 of determining whether or not a treatment is safe,
21 efficacious, or having any other characteristic of a
22 treatment which must be demonstrated in order for
23 the treatment to be medically necessary or appro-
24 priate.”.

25 (b) AMENDMENTS TO PHSA.—

1 (1) GROUP MARKET.—Subpart 2 of part A of
 2 title XXVII of the Public Health Service Act (as
 3 added by section 604(a) of the Newborns’ and Mothers’
 4 Health Protection Act of 1996 and amended by
 5 section 703(a) of the Mental Health Parity Act of
 6 1996) is amended by adding at the end the following
 7 new section:

8 **“SEC. 2706. COVERAGE FOR INDIVIDUALS PARTICIPATING**
 9 **IN APPROVED CLINICAL STUDIES.**

10 “(a) PERMITTING PARTICIPATION IN APPROVED
 11 CLINICAL STUDIES.—A group health plan, and a health
 12 insurance issuer offering health insurance coverage in con-
 13 nection with a group health plan, may not deny (or limit
 14 or impose additional conditions on) the coverage of items
 15 and services furnished to an enrollee if—

16 “(1) the enrollee is participating in an approved
 17 clinical study,

18 “(2) the items and services are furnished ac-
 19 cording to the design of the study or to treat condi-
 20 tions resulting from participation in the study, and

21 “(3) the items and services would otherwise be
 22 covered under the plan except for the fact that they
 23 are provided in connection with participation in such
 24 a study.

1 Such a plan or issuer may not discriminate against an
2 enrollee on the basis of the enrollee’s participation in such
3 a study.

4 “(b) CONSTRUCTION.—Nothing in subsection (a)
5 shall be construed as requiring a group health plan, or
6 a health insurance issuer offering health insurance cov-
7 erage in connection with a group health plan, to provide
8 for payment for items and services normally paid for as
9 part of an approved clinical study.

10 “(c) APPROVED CLINICAL STUDY DEFINED.—In this
11 section, the term ‘approved clinical study’ means—

12 “(1) a research study approved by the Sec-
13 retary of Health and Human Services, the Director
14 of the National Institutes of Health, the Commis-
15 sioner of the Food and Drug Administration, the
16 Secretary of Veterans Affairs, the Secretary of De-
17 fense, or a qualified nongovernmental research entity
18 (as defined in guidelines of the National Institutes
19 of Health), or

20 “(2) a peer-reviewed and approved research
21 program, as defined by the Secretary of Health and
22 Human Services, conducted for the primary purpose
23 of determining whether or not a treatment is safe,
24 efficacious, or having any other characteristic of a
25 treatment which must be demonstrated in order for

1 the treatment to be medically necessary or appro-
 2 priate.”.

3 (2) INDIVIDUAL MARKET.—Subpart 3 of part B
 4 of title XXVII of the Public Health Service Act (as
 5 added by section 605(a) of the Newborn’s and Moth-
 6 er’s Health Protection Act of 1996) is amended by
 7 adding at the end the following new section:

8 **“SEC. 2752. COVERAGE FOR INDIVIDUALS PARTICIPATING**
 9 **IN APPROVED CLINICAL STUDIES.**

10 “The provisions of section 2706 shall apply to health
 11 insurance coverage offered by a health insurance issuer
 12 in the individual market in the same manner as they apply
 13 to health insurance coverage offered by a health insurance
 14 issuer in connection with a group health plan in the small
 15 or large group market.”.

16 **SEC. 3. EFFECTIVE DATE.**

17 The amendment made by this Act shall apply—

18 (1) with respect to group health plans for plan
 19 years beginning on or after January 1, 1998; and

20 (2) with respect to health insurance coverage
 21 offered, sold, issued, renewed, in effect, or operated
 22 in the individual market on or after January 1,
 23 1998.

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